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A Narrative Review on the efficacy of different Transcranial Magnetic Stimulation (TMS) protocols for smoking cessation

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ADMINISTRATIVE INFORMATION

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 March 2024 and was last updated on 09 March 2024.

INTRODUCTION

Review question / Objective The primary objective of this narrative review is to critically evaluate the efficacy of Transcranial Magnetic Stimulation (TMS) protocols for smoking cessation among individuals with tobacco use disorder.

Rationale Tobacco smoking is one of the leading causes of preventable morbidity and mortality globally. Quitting smoking offers significant health benefits, notably reducing the risk of cardiovascular diseases, respiratory conditions, and various cancers. Successful smoking cessation is associated with increased life expectancy and improved mental well-being, including an improvement in mood and reduced anxiety and depression symptoms. Although promotion of smoking cessation is a vital public health initiative with far-reaching positive impacts on individuals and communities, many smokers struggle quitting due to the highly addictive nature of nicotine. Although pharmacological and non-pharmacological treatments have shown some efficacy, relapse rates remain high. TMS is a non-invasive brain stimulation technique that modulates neural activity by altering the magnetic field around nerve cells. Previous studies have demonstrated the potential of TMS in modulating neural pathways involved in nicotine dependence and withdrawal syndrome. In 2020, the FDA approved the first protocol for smoking cessation after the results of a pivotal multicenter double-blind RCT (randomized controlled trial) that established a safe treatment protocol with Deep TMS H4 coil promoting smoking cessation by stimulating relevant brain circuits. However, other stimulation protocols have been investigated to

evaluate the efficacy of TMS for the treatment of tobacco use disorder.
Given the variety of studies available, a narrative review on the impact of different TMS stimulation protocols for treating tobacco use disorder can provide a comprehensive synthesis of published evidence on this innovative topic.

Condition being studied Tobacco smoking is one of the leading causes of preventable morbidity and mortality globally. Quitting smoking offers significant health benefits, notably reducing the risk of cardiovascular diseases, respiratory conditions, and various cancers. Successful smoking cessation is associated with increased life expectancy and improved mental well-being, including an improvement in mood and reduced anxiety and depression symptoms. Although promotion of smoking cessation is a vital public health initiative with far-reaching positive impacts on individuals and communities, many smokers struggle quitting due to the highly addictive nature of nicotine. Although pharmacological and non-pharmacological treatments have shown some efficacy, relapse rates remain high. TMS is a non-invasive brain stimulation technique that modulates neural activity by altering the magnetic field around nerve cells. Previous studies have demonstrated the potential of TMS in modulating neural pathways involved in nicotine dependence and withdrawal syndrome. In 2020, the FDA approved the first protocol for smoking cessation after the results of a pivotal multicenter double-blind RCT (randomized controlled trial) that established a safe treatment protocol with Deep TMS H4 coil promoting smoking cessation by stimulating relevant brain circuits. However, other stimulation protocols have been investigated to evaluate the efficacy of TMS for the treatment of tobacco use disorder.

METHODS

Search strategy Search Strategy We will conduct a systematic search in the following databases: Cochrane CENTRAL, PubMed and Scopus databases. We will also search clinical trial databases. We will use the following search string, which we will adapt if necessary:
(TMS OR "transcranial magnetic stimulation" OR rTMS OR "repetitive transcranial magnetic stimulation" OR "repetitive TMS" OR "high frequency rTMS" OR "low frequency rTMS" OR "theta burst stimulation" OR “TBS” OR "theta burst" OR cTBS OR "continuous theta burst stimulation" OR iTBS OR "intermittent theta burst stimulation" OR " accelerated rTMS" OR "accelerated HF-rTMS" OR "HF-rTMS") AND (Smoking OR tobacco OR “cigarette*” OR “smoking cessation" OR "tobacco cessation" OR "quit smoking" OR “smoking quit*“ OR “quitting smoking” OR ”smoking intervention" OR "tobacco intervention" OR “tobacco addiction” OR “smoking addiction” OR “Smoking dependence” OR “Tobacco use disorder”).

Participant or population We will include adults with a confirmed DSM5/5-TR diagnosis of tobacco use disorder.

Intervention We will incorporate research that utilizes various TMS techniques to treat tobacco use disorder. This includes both high and low-frequency repetitive transcranial magnetic stimulation (rTMS), as well as accelerated HF-rTMS and LF-rTMS, and theta-burst stimulation (TBS). The TBS methods encompass continuous theta-burst stimulation (cTBS) and intermittent theta-burst stimulation (iTBS). We will include studies in which TMS or TBS are delivered both as monotherapy or as add-on treatment.

Comparator Sham (fictitious) stimulation or other active stimulations.

Study designs to be included We will include randomized controlled trials (RCTs), both with parallel group or cross-over design.

Eligibility criteria All the following criteria must be met for inclusion:1. Participants: adults with a confirmed DSM5/5-TR diagnosis of tobacco use disorder;2. Intervention: studies focusing on the use of TMS, either as a monotherapy or as an add-on administration. This encompasses both HF-rTMS and LF-rTMS, cTBS and iTBS. We will also include studies with a-rTMS;3. Comparator: sham (fictitious) stimulation as well as other active stimulations;4. Study design: RCTs trials, both parallels group and cross-over design;5. Outcomes: Changes in nicotine or tobacco craving, changes in smoking cessation rate, changes in cognitive functions, changes in withdrawal symptoms, changes in mood, changes in anxiety, changes in quality of life, changes in sleep quality, side effects.6. Language: English

Information sources We will conduct a systematic search in the databases: Cochrane CENTRAL, PubMed and Scopus databases.

Main outcome(s)
1. Smoking cessation (self reported and biologically validated).

Additional outcome(s)

1. Smoking reduction (self reported and biologically validated)
2. Changes in tobacco craving
3. Changes in withdrawal symptoms
4. Changes in cognitive functions
5. Treatment side effects.

Data management Data will be extracted into a relational database by two independent reviewers. Any discrepancies will be resolved by a third experienced author. We do not aim to conduct any kind of quantitative analysis (e.g. meta-analysis) among the outcomes' extracted data.

Quality assessment / Risk of bias analysis We will not assess Risk of bias among primary studies.

Strategy of data synthesis In order to syntetize evidence, we will conduct a qualitative data synthesis process and present descriptive tables throughout the manuscript.

Subgroup analysis We do not plan any subgroup analysis.

Sensitivity analysis We do not plan any sensitivity analysis.

Language restriction English, Italian.

Country(ies) involved Italy, Germany.

Keywords Nicotine, tobacco, smoking, dependence, TMS, Non-Invasive Brain Stimulation, NIBS.

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